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ATTORNEY DOCKET No. 22253-69814

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: ROSTAMI et al.

Application No.: 09/943,688

Filed: August 31, 2001

Entitled: USE OF BOWMAN BIRK INHIBI-
TOR FOR THE TREATMENT OF MS AND
OTHER AUTOIMMUNE
DISEASES

Group Art Unit: 1653

Examiner: not yet assigned

Assistant Commissioner for Patents
Washington, D.C. 20231

VIA FEDERAL EXPRESS OVERNIGHT
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INFORMATION DISCLOSURE STATEMENT

Sir:

Listed on the accompanying Form PTO-1449 are documents which may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. All of the aforesaid reported references are respectfully requested to be considered in connection with examination of this application, and to be made of record herein.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application.

Date: July 8, 2002

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U.S. PATENT DOCUMENTS

EXAMINER INITIALS	Cite No.	DOCUMENT NUMBER	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	A	4,793,996	<i>Kennedy, et al.</i>	12/27/1988	
	B	5,217,717	<i>Kennedy, et al.</i>	06/08/1993	
	C	5,338,547	<i>Kennedy, et al.</i>	08/16/1994	
	D	5,616,492	<i>Kennedy, et al.</i>	04/01/1997	
	E	5,618,679	<i>Kennedy, et al.</i>	04/08/1997	
	F	5,961,980	<i>Kennedy, et al.</i>	10/05/1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Office	DOCUMENT NUMBER	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T

OTHER PRIOR ART--NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	1	Atkinson, SJ, Ward, RV, Reynolds, JJ, "Cell-mediated degradation of type IV collagen and gelatin films is dependent on the activation of matrix metalloproteinases," <i>Biochem. J.</i> 288:605-611 (1992)	
	2	Bai, X.F., F.D. Shi, J. Zhu, B.G. Xiao, G. Hedlund, and H. Link, "Linomide-induced suppression of experimental autoimmune neuritis is associated with down-regulated macrophage functions," <i>J. Neuroimmunol.</i> 76:177 (1997).	

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	3	Bar-Or A, Oliveira EM, Anderson DE, Hafler DA, "Molecular pathogenesis of multiple sclerosis," <i>J. Neuroimmunol.</i> 100:252-259 (1999).	
	4	Bever, CT Jr, Rosenberg, GA, "Matrix metalloproteinases; in multiple sclerosis: targets of therapy or markers of injury?" <i>Neurology</i> 53:1380-1381 (1999).	
	5	Billings PC, "Approaches to studying the target enzymes of anticarcinogenic protease inhibitors," In <i>Protease Inhibitors as Cancer Chemopreventive Agents</i> , Troll W, Kennedy AR (eds.), New York, Plenum Press, 1993, pp. 191-198.	
	6	Billings, PC, Brandon, DL, Habres, JM, "Internalization of the Bowman-Birk protease inhibitor by intestinal epithelial cells," <i>Eur. J. Canc.</i> 27:903-908 (1991B)	
	7	Billings, PC, Clair, WHS, Maki, PA, Kennedy, AR, "Distribution of the Bowman-Birk inhibitor in mice following oral administration," <i>Canc. Lett.</i> 62:191-197 (1992)	
	8	Billings, PC, Habres, JM, Liao, DC, Tuttle, SW, "Human Fibroblasts Contain a Proteolytic Activity Which Is Inhibited by the Bowman-Birk Protease Inhibitor," <i>Cancer Res.</i> 50:5539-5543 (1991A)	
	9	Birk, Y, "Protease Inhibitors of Plant Origin and the Role of Protease Inhibitors in Human Nutrition," In <i>Protease Inhibitors as Cancer Chemopreventive Agents</i> . Troll W, Kennedy AR (eds). New York, Plenum Press, 1993, pp. 97-106	
	10	Birk, Y, "Proteinase inhibitors from plant sources," <i>Meth. Enzymol.</i> 45:695-751 (1975)	
	11	Birk, Y, "The Bowman-Birk Inhibitor," <i>J. Peptide Protein Res.</i> 25:113-134 (1985)	

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	12	Boccaccio, GL, Steinman, L, "Multiple sclerosis: from a myelin point of view," <i>J. Neurosci. Res.</i> [volume 45]:647-654 (1996)	
	13	Bowman, DE, "Fractions derived from soybeans and Navy beans which retard tryptic digestion of casein," <i>Proc. Soc. Exp. Biol. Med.</i> 57:139-140 (1944)	
	14	Bowman, DE, "Further identification of bean trypsin inhibiting factors," <i>Arch. Biochem. Biophys.</i> 16:109-113 (1948)	
	15	Brosnan, CR, Caminer, W, Norton, WT, Bloom, BR, "Proteinase inhibitors suppress the development of experimental allergic encephalomyelitis," <i>Nature</i> 285:235-237 (1980).	
	16	Brostoff, SW, Burnett, P, Lampert, PW, Eylar, EH, "Isolation and characterization of a protein from sciatic nerve myelin responsible for experimental allergic neuritis," <i>Nat. New Biol.</i> 235:210-212 (1972)	
	17	Clements, JM, Cossins, JA, Wells, GM, Corkill, DJ, Helfrich, Y, Wood, LM, Pigott, R, Stabler, G, Ward, GA, Gearing, AJ, Miller, KM, "Matrix metalloproteinase expression during experimental autoimmune encephalomyelitis and effects of a combined matrix metalloproteinase and tumour necrosis factor-alpha inhibitor," <i>J. Neuroimmunol.</i> 74:85-94 (1997)	
	18	Constantinescu, C.S., Wysocka, M., Hilliard, B., Venyura, E.S., Lavi, E., Trinchieri, G. and Rostami, A., "Antibodies Against IL-12 Prevent Superantigen-Induced and Spontaneous Relapses of Experimental Autoimmune Encephalomyelitis," <i>J. Immunol.</i> 161:5097-5104 (1998)	
	19	Constantinescu, CS, Hilliard, B, Fujioka, T, Bhopale, MK, Calida, D, Rostami, AM, "Pathogenesis of Neuroimmunologic Diseases: Experimental Models," <i>Immunologic Res.</i> 17:217-227 (1998)	

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	20	Cuzner ML, Opdenakker G, "Plasminogen activators and matrix metalloproteases, mediators of extracellular proteolysis in inflammatory demyelination of the central nervous system," <i>J. Neuroimmunol.</i> 94:1-14 (1999)	
	21	Cuzner, MI, Norton, WT, "Biochemistry of demyelination," <i>Brain Pathol.</i> [volume 6] 231-242 (1996A)	
	22	Dietsch, GN, Hinrichs, DJ, "Mast cell proteases liberate stable encephalitogenic fragments from intact myelin," <i>Cell. Immunol.</i> 135:541-548 (1991)	
	23	Evans <i>et al.</i> , <i>Radiat. Res.</i> 132:259-262 (1992) "Protection against Metastasis of Radiation-Induced Thymic Lymphosarcoma and Weight Loss in C57Bl/6NCr1BR Mice by an Autoclave-Resistant Factor Present in Soybeans".	
	24	Frenkel, K, Chrazan, K, Ryan, CA, Wiesner, R, Troll, W, "Chymotrypsin-specific protease inhibitors decrease H2O2 formation by activated human polymorphonuclear leukocytes," <i>Carcinogenesis</i> 8:1207-1212 (1987)	
	25	Fujioka, T., E. Purev, and A. Rostami, "Chemokine mRNA expression in the cauda equina of Lewis rats with experimental allergic neuritis," <i>J. Neuroimmunol.</i> 97:51 (1999).	
	26	Fujioka, T., T. Jimi, B.A. Hilliard, E.S. Ventura, and A. Rostami, "The expression of cytokine mRNA in the cauda equina of Lewis rats with experimental allergic neuritis," <i>J. Neuroimmunol.</i> 84:223 (1998)	
	27	Gijbels, K, Galardy, RE, Steinman, L, "Reversal of experimental autoimmune encephalomyelitis with a hydroxamate inhibitor of matrix metalloproteases," <i>J. Clin. Invest.</i> 94:2177-2182 (1994)	
	28	Gladysheva, IP, Larionova, NI, Gladyshev, DP, Tikhonova, TV, Kazanskaia, NF, "The classical Bowman-Birk soy inhibitor is an effective inhibitor of human granulocyte alpha-chymotrypsin and cathepsin G," <i>Biochemistry (Moscow)</i> 59(4):513-518 (1994)	

COPY

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	29	Gold, R., J.J. Archelos, and H.P. Hartung, "Mechanisms of immune regulation in the peripheral nervous system," <i>Brain Pathol.</i> 9: 343 (1999)	
	30	Halonen, T, Kilpelainen, H, Pitkanen, A, Riekkinen, PJ, "Lysosomal hydrolases in cerebrospinal fluid of multiple sclerosis patients," <i>J. Neurol. Sci.</i> 79:267-274 (1987)	
	31	Hartung, HP, Kieseier, BC, "The role of metalloproteinases in autoimmune damage to the central and peripheral nervous system," <i>J. Neuroimmunol.</i> 107:140-147 (2000)	
	32	Hauser, SL, Goodkin, DE, "Multiple Sclerosis and Other Demyelinating Diseases," In <i>Harrison's Principles of Internal Medicine</i> . Fauci <i>et al.</i> (eds). New York, McGraw-Hill, 1998, pp. 2409-2419	
	33	Hawkins, JV, Emmel, EL, Feuer, A, Nedelman, MA, Harvey, CJ, Klein, HJ, Rozmiarek, J, Kennedy, AR, Lichtenstien, GR, Billings, PC, "Protease activity in a hapten-induced model of ulcerative colitis in rats," <i>Digestive Diseases and Sciences</i> 42:1969-1980 (1996)	
	34	Hewson, AY, Smith, T, Leonard, JP, Cuzner, ML, "Suppression of experimental allergic encephalomyelitis in the Lewis rat by the matrix metalloproteinase inhibitor Ro31-9790," <i>Inflamm. Res.</i> 44:345-349 (1995)	
	35	Ibrahim, MZM, Reder, AT, Lawand, R, Takash, W, Sallouh-Khatib, S, "The mast cells of the multiple sclerosis brain," <i>J. Neuroimmunol.</i> 70:131-138 (1996)	
	36	Kennedy, AR, "Anticarcinogenic activity of protease inhibitors: Overview," In <i>Protease-Inhibitors as Cancer Chemopreventive Agents</i> , Troll, W, Kennedy, AR (eds). New York, Plenum Press, 1993A, pp. 9-64	
	37	Kennedy, AR, "Cancer prevention by protease inhibitors," <i>Preventive Med.</i> 22:796-811 (1993C)	

COPY

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	38	Kennedy, AR, "Chemopreventive Agents: Protease Inhibitors," <i>Pharmacological Therapeutics</i> 78:167-209 (1998)	
	39	Kennedy, AR, "Mechanisms. of cancer prevention: Effects of protease inhibitors on protease and gene expression," In <i>Nutrients in Cancer Prevention and Treatment</i> , Prasad (ed) 1995B, pp. 71-82	
	40	Kennedy, AR, "Prevention of carcinogenesis by protease inhibitors," <i>Cancer Res.</i> (suppl) 54:1999s-2005s (1994)	
	41	Kennedy, AR, "The evidence for soybean products as cancer preventive agents," <i>J. Nutr.</i> 125:733s-743s (1995C)	
	42	Kennedy, AR, Letter to the editor, <i>J. Nutr.</i> 126:584-585 (1996)	
	43	Kennedy, AR, Little, JB, "Protease, inhibitors suppress radiation induced malignant transformation <i>in vitro</i> ," <i>Nature</i> 276:825-826 (1978)	
	44	Kennedy, AR, Manzone, H, "Effects of protease inhibitors on levels of proteolytic activity in normal and pre-malignant cells and tissues," <i>J. Cell. Biochem.</i> 22:188-194 (1995A)	
	45	Kennedy, AR, Szuhaj, BF, Newberne, PM, Billings, PC, "Preparation and production of a cancer chemopreventive agent, Bowman-Birk Inhibitor Concentrate," <i>Nutr. Cancer</i> 19:281-302 (1993B)	
	46	Kieseier, BC, Storch, MK, Archelos, JJ, Martino, G, Hartung, HP, "Effector pathways in immune mediated central nervous system demyelination," <i>Curr. Opin. Neurol.</i> 12:323-336 (1999)	
	47	Kremlev, S.G., A.I. Chapoval, and R. Evans, "Cytokine release by macrophages after interacting with CSF-1 and extracellular matrix proteins: characteristics of a mouse model of inflammatory responses <i>in vitro</i> ," <i>Cell. Immunol.</i> 185:59 (1998)	

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	48	Larionova, NI, Gladysheva, IP, Tikhonova, TV, Kazanskaia, NF, "Inhibition of cathepsin G and elastase from human granulocytes by multiple forms of the Bowman-Birk type of soy inhibitor," <i>Biochemistry (Moscow)</i> 58:1437-44 (1993)	
	49	Maeda, A, Sobel, RA, "Matrix metalloproteinases in the normal human central nervous system, microglial nodules, and multiple sclerosis lesions," <i>J. Neuropathol. Experimental Neurol.</i> 55:300-309 (1996)	
	50	Maki, <i>et al.</i> , "Studies Related to the Potential Antigenicity of the Bowman-Birk Inhibitor, an Anticarcinogenic Protease Inhibitor Isolated From Soybeans", <i>Nutr. Cancer</i> 22:185-193 (1994).	
	51	Malkowicz, SB, McKenna, W.G., Vaughn, DJ, Wan, XS, Propert, KJ, Rockwell, K, Marks, SHF, Wein, AJ, Kennedy, AR, "Effects of Bowman-Birk Inhibitor Concentrate in patients with benign prostatic hyperplasia," <i>The Prostate</i> 48:16-28 (2001)	
	52	Meyskens, FL, Armstrong, WB, Wan, XS, Taylor, TH, Jenson, J, Thompson, W, Nguyen, QA, Kennedy, AR, "Bowman-Birk inhibitor concentrate (BBIC) affects oral leukoplakia lesion size, neu protein levels and proteolytic activity in buccal mucosal cells," <i>Proc. Amer. Assoc. Cancer Res.</i> 40:Abstract #2855 (1999)	
	53	Murphy, G, Atkinson, S, Ward, R, "The role of plasminogen activators in the regulation of connective tissue metalloproteinases," <i>Ann. N.Y. Acad. Sci.</i> 667:1-12 (1992)	
	54	Odani, S, Ikenaka, T, "Studies on soybean trypsin inhibitors VII. Disulfide bridges in soybean Bowman-Birk proteinase inhibitor," <i>J. Biochem.</i> 74:697-715 (1973)	
	55	Opdenakker, G, Van Damme, J. "Cytokine-regulated proteases in autoimmune diseases," <i>Immunol. Today</i> 15:103-107 (1994)	
	56	Owens, T., T. Renno, V. Taupin, and M. Krakowski, "Inflammatory cytokines in the brain: does the CNS shape immune responses?" <i>Immunol. Today.</i> 15:566 (1994)	

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	57	Page, JG, Heath, JE, May, RD, and Martin, JF, "13-week toxicity study of Bowman Birk Inhibitor Concentrate (BBIC) in rats," SRI-CBE-94-060-7482, Southern Research Institute, Birmingham, AL (1994)	
	58	Page, JG, Rodman, LE, Giles, HD, Farnell, DR and Wood, RD, "13-week toxicity study of Bowman Birk Inhibitor Concentrate (BBIC) in dogs," SRI-CBE-94-135-7482, Southern Research Institute, Birmingham, AL (1994)	
	59	Raine CS, "The Dale E. McFarlin Memorial Lecture: the immunology of the multiple sclerosis lesion," <i>Ann. Neurol.</i> 36:S61-72 (1994)	
	60	Raine, CS, "Demyelinating Diseases," In <i>Textbook of Neuropathology</i> . Davis RL (ed) Baltimore, MD, Williams and Wilkins, 1990, pp. 356-358	
	61	Rivers, TM, Sprunt, DH, Berry, GP, "Observations on attempts to produce acute disseminated encephalomyelitis in monkeys," <i>J. Exp. Med.</i> 58:39-53 (1933)	
	62	Romanic, AM, Madri, JA, "Extracellular matrix-degrading proteinases in the nervous system," <i>Brain Pathol.</i> 4:145-156 (1994)	
	63	Rosen, J.L., M. Brown, and A. Rostami, "Evolution of the cellular response in P2-induced experimental allergic neuritis," <i>Pathobiology</i> 60:108 (1992)	
	64	Rosen, JL, Brown, MJ, Hickey, WF, Rostami, AM, "Early myelin lesions in experimental allergic neuritis," <i>Muscle and Nerve</i> 13:629-636 (1990)	
	65	Rostami, AM, "Guillain-Barre syndrome: clinical and immunological aspects," <i>Springer Semin. Immunopathol.</i> 17:29-42 (1995)	

COPY**INFORMATION DISCLOSURE
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	66	Rostami, AM, Brown, MJ, Lisak, RP, Sumner, AJ, Zweiman, B, Pleasure, DE, "The role of Myelin P2 protein in the production of experimental allergic neuritis," <i>Ann. Neurol.</i> 16:680-685 (1984)	
	67	Rostami, AM, Gregorian, SK, Brown, MJ, Pleasure, DE, "Induction of severe experimental autoimmune neuritis with a synthetic peptide corresponding to the 53-78 amino acid sequence of the myelin P2 protein," <i>J. Neuroimmunol.</i> 30:145-151 (1990)	
	68	Serota, DG, "One-year oral toxicity study of Bowman Birk Inhibitor Concentrate in Dogs., 560-058, MPI Research, Inc., Mattawan, MI (2000)	
	69	Serota, DG, "Six-month oral toxicity study of Bowman-Birk Inhibitor Concentrate in mice," 560-057, MPI Research, Inc., Mattawan, MI (2000)	
	70	Shang, X.Z., B.J. Lang, and A.C. Issekutz, "Adhesion molecule mechanisms mediating monocyte migration through synovial fibroblast and endothelium barriers: role for CD11/CD18, very late antigen-4 (CD49d/CD29), very late antigen-5 (CD49e/CD29), and vascular cell adhesion molecule-1 (CD106)," <i>J. Immunol.</i> 160:467 (1998)	
	71	St. Clair <i>et al.</i> , "Suppression of Dimethylhydrazine-induced Carcinogenesis in Mice by Dietary Addition of the Bowman-Birk Protease Inhibitor", <i>Cancer Res.</i> 50:580-586 (1990)	
	72	Tikhonova, TV, Gladysheva, IEP, Kazanshaya, NF, Larionova NI, "Hydrolysis of elastin by human leukocyte elastase and cathepsin G: Inhibition by Bowman Birk type inhibitor," <i>Biochemistry (Moscow)</i> 59:1295-1299 (1994)	
	73	Vaday GG, Lider O, "Extracellular matrix moieties, cytokines, and enzymes: dynamic effects on immune cell behavior and inflammation," <i>J. Leukoc. Biol.</i> 67:149-159 (Feb., 2000)	

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	74	Vaddi K- and R.C. Newton, "Regulation of monocyte integrin expression by Beta-family chemokines," <i>J. Immunol.</i> 153:4721 (1994)	
	75	van Hofe <i>et al.</i> , "Inhibition of N-nitrosomethylbenzylamine-induced esophageal neoplasms by the Bowman-Birk protease inhibitor", <i>Carcinogenesis</i> 12:2147-2150 (1991)	
	76	Waksman, BH, Adams, RD, "Allergic neuritis? An experimental disease of rabbits induced by the injection of peripheral nervous tissue and adjuvants," <i>J. Exp. Med.</i> 102:213-236 (1955)	
	77	Wan <i>et al.</i> , "Relationship between Protease Activity and <i>neu</i> Oncogene Expression in Patients with Oral Leukoplakia Treated with the Bowman Birk Inhibitor", <i>Cancer Epidem. Biomarkers & Prevention</i> 8:601-608 (1999)	
	78	Wan, XS, Koch, CJ, Lord, EM, Manzone, H, Billings, PC, Donahue, JJ, Odell, C, Miller, JH, Schmidt, NA, Kennedy, AR, "Monoclonal antibodies differentially reactive with native and reductively modified Bowman-Birk protease inhibitor," <i>J. Immunol. Meth.</i> 180:117-130 (1995)	
	79	Ware, JH, Wan, XS, Kennedy, AR, "The Bowman-Birk Inhibitor Suppresses Production of Superoxide Anion Radicals in Differentiated HL-60 Cells," <i>Cancer and Nutrition</i> 33:174-177 (1999)	
	80	Ware, JH, Wan, XS, Newberne, P, Kennedy, AR, "Bowman-Birk Inhibitor Concentrate reduces colon inflammation in mice with dextran sulfate sodium-induced ulcerative colitis," <i>Digestive Diseases and Sciences</i> 44:896-90 (1999)	
	81	Ware, JH, Wan, XS, Rubin, H, Schechter, NM, Kennedy, AR, "Soybean Bowman-Birk protease inhibitor is a highly effective inhibitor of human mast cell chymase," <i>Arch. Biochem. Biophys.</i> 344:133-138 (1997)	

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	82	Weber, C., R. Alon, B. Moser, and T.A. Springer, "Sequential regulation of alpha 4 beta 1 and alpha 5 beta 1 integrin avidity by CC chemokines in monocytes: implications for transendothelial chemotaxis," <i>J Cell. Biol.</i> 134:1063 (1996)	
	83	Wucherpfennig KW, Catz I, Hausmann S, Strominger JL, Steinman L, Warren KG, "Recognition of the immunodominant myelin basic protein peptide by autoantibodies and HLA-DR2-restricted T cell clones from multiple sclerosis patients. Identity of key contact residues in the B-cell and T-cell epitopes," <i>J. Clin. Invest.</i> 100(5):1114-1122 (1997)	
	84	Yavelow, J, Collins, M, Birk, Y, Troll, W, Kennedy, AR, "Nanomolar concentrations of Bowman-Birk soybean protease inhibitors suppress X-ray induced transformation in vitro," <i>Proc. Nat'l. Acad. Sci. USA</i> 82:5395-5399 (1985)	
	85	Yavelow, J, Finlay, TH, Kennedy, AR, Troll, W, "Bowman-Birk soybean protease inhibitor as an anticarcinogen," <i>Cancer Res.</i> 43:2454-2459 (1983)	